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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,088	07/26/2001	Alessandro Lambiase	026073.00020	6075

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ARENT FOX LLP
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WASHINGTON, DC 20036

EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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07/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
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Office Action Summary	Application No. 09/890,088	Applicant(s) LAMBIASE, ALESSANDRO	
	Examiner CHERIE M. WOODWARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009 and 04 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 19-21, 24-27 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 19-21, 24-27 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

1. Applicant's Response and Amendments filed 10/29/2009 and 5/4/2010 are acknowledged and entered. Claims 1-12, 16, 17, 22, 23, 28, and 29 have been cancelled. Claims 13-15, 18-21, 24-27, and 30-36 are pending and under examination.

Priority

2. The translation of Foreign Priority Document – Italy RM99A00069 (1/29/1999) is acknowledged. Priority is granted to 1/29/1999.

Response to Arguments

Rejections/Objections Withdrawn

3. The objection to the title is withdrawn in light of Applicant's amendment.
4. The rejection of claims 13, 21, and 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for new matter is withdrawn in light of Applicant's clarification and citation of page 22, line 25 and Table 4 on page 25 of the specification.
5. The rejection of claims 13-15, 18-21, 24-27 and 30-36 under 35 U.S.C. 102(b) as being anticipated by Lambiase (WO 98/48002), as evidenced by Steadman's Medical Dictionary (Lippincott Williams & Wilkins, 2000) and *The World's Best Anatomical Charts* (Anatomical Chart Company, Skokie, IL, 2000) (Sagittal View of the Eye), is withdrawn. A new rejection, necessitated by amendment is set forth below.

Rejections/Objections Maintained

Obviousness-Type Double Patenting Rejection

6. The rejection of claims 13, 15, 18, 19, 20, 21, 24-27, 30, 31, 33, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-11, and 13 of copending Application No. 12/064,172, is maintained.

Applicant argues that the claims of the '172 are directed to affect the central nervous system and that the optic nerve is a "peripheral nerve" (Remarks filed 5/4/2010, page 2). Applicant also argues that

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the instant rejection is "not required at this time" and that it should be held in abeyance (Remarks filed 5/4/2010, page 2).

Applicant's arguments have been fully considered, but they are not persuasive. As stated in the Notice of Non-Compliant Amendment mailed 12/4/2009, a rejection may not be held in abeyance. Applicant is not required to submit a Terminal Disclaimer, but must respond to each and every rejection presented in an Office Action. Applicant's arguments that the '172 application is directed to the effects on the central nervous system and that the optic nerve is a peripheral nerve is not persuasive. The optic nerve is, as applicant notes, a cranial nerve. JP 10-218787 (cited in Response to Applicant's argument) is provided as an evidentiary reference to show that topically administered NGF is known to be useful in the treatment of the optic nerve due to intracranial disease (see claim 7) (machine translation provided herein). Additionally, JP 10-218787 teaches treatment of cranial nerve disease comprising administering topical NGF and that the NGF is capable of undergoing retrograde axonal transport to the central nervous system via the optic nerve (claim 9; paragraph 37).

Applicant is also reminded that the merits of a provisional obviousness-type double patenting rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966).

The provisional obviousness-type double patenting rejection is maintained.

New Claim Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 13-15, 18-21, 24-27, and 30-36 are rejected under 35 U.S.C. 103(a) as being obvious over Okamoto, JP 10-218787 (18 August 1998) (cited on Applicant's IDS of 7/26/2001; machine language translation provided herewith).

The Examiner finds the following facts:

- a. Okamoto teaches methods of treating pathologies of the eye including the retina and optic nerve by topical administration of NGF to treat glaucoma (abstract; claims; paragraphs 7, 8, and 18). Ophthalmic ointments and solutions, including eye drops, comprising NGF are taught at paragraphs 8 and 21-31. The concentration of NGF is taught at paragraph 51 as being in the range of 10µg/250ml to 0.1µg to about 100mg/250ml and is also taught as being readily optimizable by the person of ordinary skill in the art depending on the intended use and pharmaceutical form. Administration using a contact lens absorbent is taught in the abstract and at paragraph 33. Viscous agents including polymers are taught at paragraph 29.
- b. A person of ordinary skill in the art at the time the invention was made would have reasonably known that dosages are results-effective variables which can be optimized. In the case of administering NGF, one of skill in the art would clearly recognize that doses could easily be optimized depending on the intended use and pharmaceutical form, as taught by Okamoto. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977; and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)).
- c. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

In view of the facts recited above, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention, as set forth above. One of skill in the art would have recognized that the results of the optimization of

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ranges would have yielded nothing more than predictable results to one of ordinary skill in the art at the time the invention was made, as taught by Okamoto.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/

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Primary Examiner, Art Unit 1647